

be eccentrically or irregularly shaped and/or may be keyed in order to deter incorrect installation or usage.

[0050] In some embodiments, the reservoir or compartment may be a partially collapsible non pressurized reservoir. This may advantageously prevent the buildup of air in the reservoir as the fluid in the reservoir is depleted. The reservoir may be connected to the fluid path through a septum (not shown). Air buildup in a vented reservoir could prevent fluid egress from the reservoir, especially if the system is tilted so that an air pocket intervenes between the fluid contained in the reservoir and the septum of the reservoir. Tilting of the system may be expected during normal operation when used in a wearable device.

[0051] The flow of fluid from the various compartments through the fluid lines **39** may be controlled by active valves or passive valves. In some embodiments a pumping mechanism may be located downstream from the compartment to actuate the valves. The configuration may be similar to the pumping mechanisms described in U.S. Patent Application 2007/0219480. In some embodiments, the pumping mechanism is actuated using at least one shape memory actuator (e.g., a conductive shape-memory alloy wire) that changes shape with temperature. The temperature of the shape-memory actuator(s) may be changed with a heater, or more conveniently, by application of an electric current. In one embodiment, the shape memory actuator is a shape memory wire constructed of nickel/titanium alloy, such as NITINOL™ or FLEXINOL®.

[0052] The substrate **37** together with the plurality of microneedles may be akin to a cannula such as those used with insulin pumps and other infusion delivery devices. The substrate may include a second layer over the fluid pathways. In these embodiments, the fluid paths are sandwiched within the substrate. The substrate may also include an adhesive layer on the patient side of the substrate. In some embodiments, the cannula may also be incorporated into a spring-based auto-inserter system similar to those found in the art.

[0053] Referring now to FIG. 4, an insulin pen apparatus **40** is shown. This embodiment includes at least one microneedle **46** on the end of a pen housing **42**. Thus, in some embodiments, the substrate is attached to the end of the pen housing. In other embodiments, the microneedles may be manufactured on a substrate that is a pen housing. The microneedle(s) **46** are fluidly connected to a needle **44**. The pen apparatus **40** may be attached to the end of an insulin pen, for example, one known in the art, and in this attachment process, the needle **44** penetrates the septum of the insulin pen. Insulin is able to flow from the insulin pen, through the needle and through the microneedles **46** into the patient. Greater numbers of microneedles **46** enable quicker delivery of a volume of insulin and will allow delivery over a greater patient surface area. The microneedles **46** used in these embodiments may be any microneedles including those described and shown above with respect to FIGS. 1-2.

[0054] In another embodiment, at least one microneedle, for example, in some embodiments, the embodiments shown in either FIG. 1 or FIG. 2, is incorporated as part of an analyte sensor. The at least one microneedle may be used as an introduction needle for the analyte sensor or in conjunction with the analyte sensor. In some embodiments, the microneedles may be incorporated as a fluid delivery device to fluids to provide for example, insulin therapy, chemotherapies, vitamins, painkillers, antibacterials, antimicrobi-

als or any other therapeutic or nutritive fluid or compound therapy. The microneedles as shown in FIG. 1 or FIG. 2, and other known in the art, may be used in conjunction with an insulin pump, whether a syringe pump or a patch pump. The microneedles may be used in conjunction with any device that delivers a therapeutic or nutritive fluid and may be used to deliver more than one type of fluid as part of the same device, delivering the fluid(s) when requested and of the volume requested, either by a patient, microprocessor or device. In some embodiments, the microneedles are used to deliver a given volume of fluid quicker or over a larger surface area.

[0055] Referring now to FIG. 5, in one embodiment, at least one microneedle **50** is located on the end of at least one fluid path **52** or sensor paths. In embodiments including multiple fluid paths **52**, the fluid paths **52** and paths **52** are spaced appropriate for delivery, i.e. depending on the fluid(s) being delivered and/or the sensor; it may be desired for the various fluid paths and paths to be a given/specific distance from one another. In some embodiments, paths are used to hold a microneedle apparatus **50** which may be an analyte sensor. Thus, in some other embodiments, one or more fluid paths **52** contain at least one microneedle **50** for fluid delivery of either the same or different fluid, and at least one arm contains at least one microneedle for analyte sensing. The manifold or housing **54** contains one or more fluids to be delivered and can additionally include valves in the fluid lines for pulsed or controlled delivery. Additionally, the manifold may be connected to a pumping mechanism that may control the pulses and provide for controlled volumetric delivery of fluids. In various embodiments, the length of the fluid paths or path and the spacing between them may be any length desired for the particular purpose.

[0056] While the principles of the invention have been described herein, it is to be understood by those skilled in the art that this description is made only by way of example and not as a limitation as to the scope of the invention. Other embodiments are contemplated within the scope of the present invention in addition to the exemplary embodiments shown and described herein. Modifications and substitutions by one of ordinary skill in the art are considered to be within the scope of the present invention.

What is claimed is:

1. A medical system comprising:
 - a reservoir partially collapsible for containing an infusible fluid, the reservoir comprising an integral septum;
 - a fluid path fluidly connected to the reservoir; and
 - a plurality of microneedles fluidly connected to the reservoir by the fluid path, each microneedle having a body portion and two appendages,
 wherein the reservoir is fluidly connected to the fluid path by a needle penetrating the septum on the reservoir.
2. The medical system of claim 1 wherein the body portion of each microneedle is made from a first material and the appendages of each microneedle are made from a second material.
3. The medical system of claim 2 wherein the second material is different from the first material.
4. The medical system of claim 3 wherein the second material is dissolvable.
5. The medical system of claim 1 wherein the appendages provide for microneedle retention.
6. The medical system of claim 1 wherein the reservoir is a non-pressurized.